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(54) Medical instrument

(57) A medical instrument, e.g. a catheter 4 or swab 9 for insertion into the urethra has an introducer portion for isolating the instrument body from bacteria at the outer end of the urethra comprising a sheath 5 impervious to bacteria and having a closed end 7 which opens on application of pressure from within the sheath 5 to form an aperture for passage of the catheter or swab. The arrangement prevents bacteria being carried along the urethra by the act of inserting the instrument body as the sheath 5 is inserted only to a limited extent so that the catheter or swab emerges from it in an area clear of bacteria.

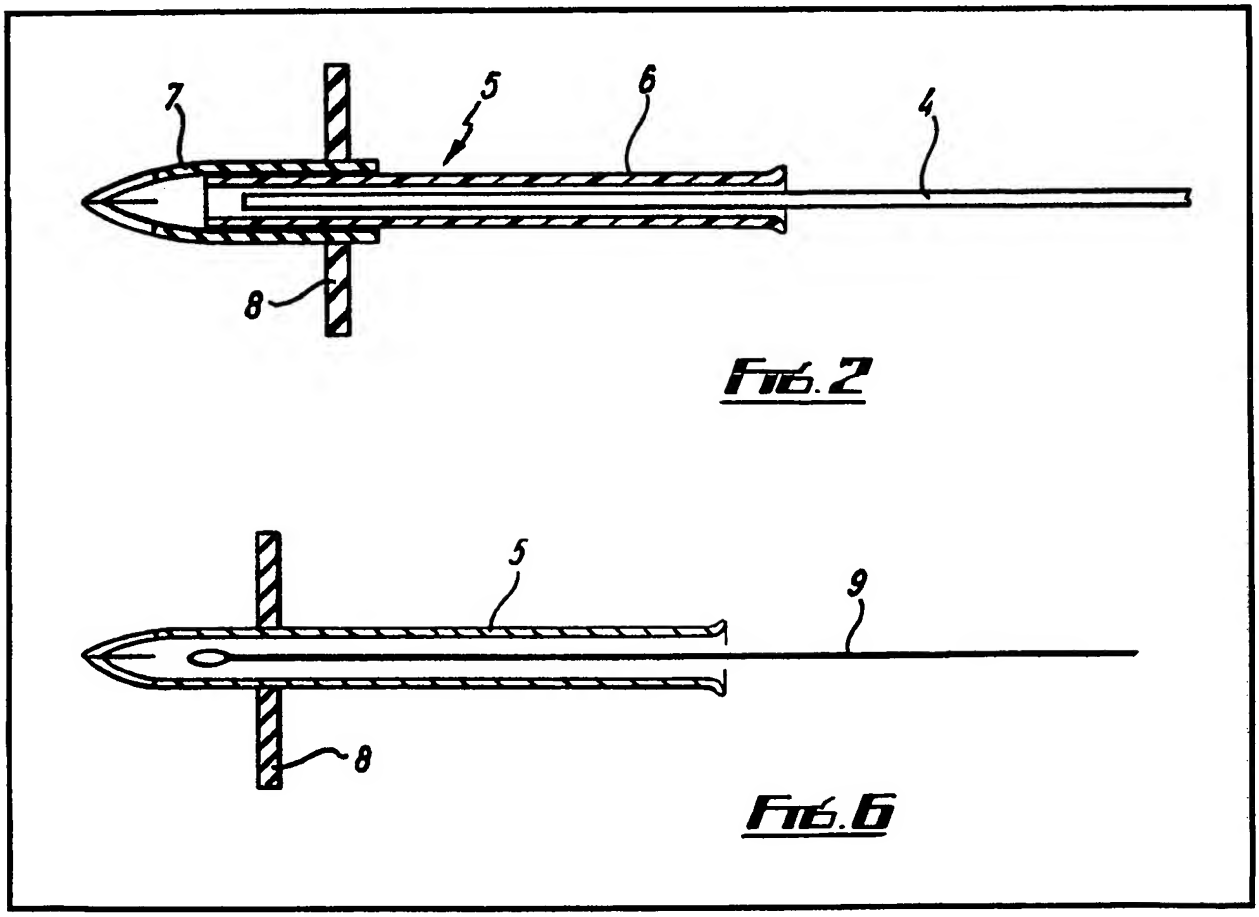

FIG. 2

FIG. 6

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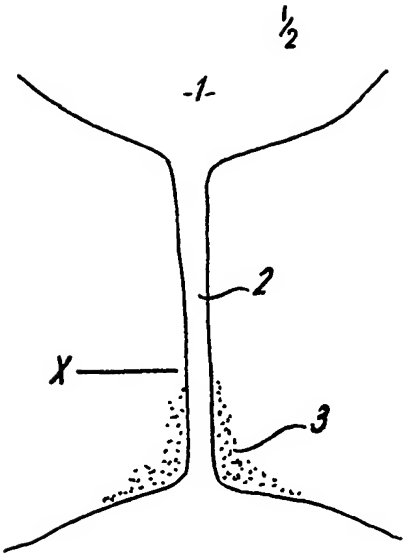

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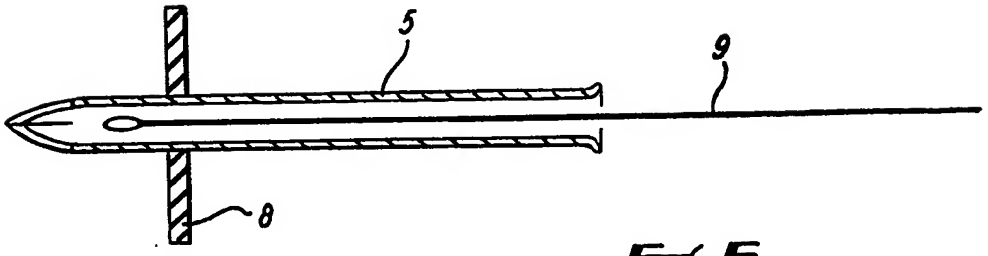

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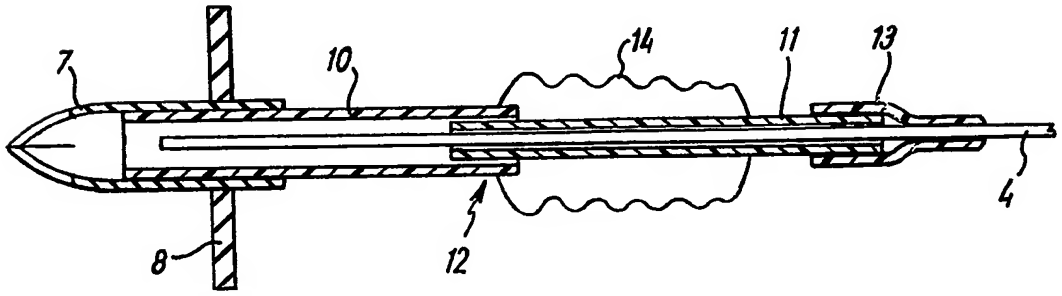

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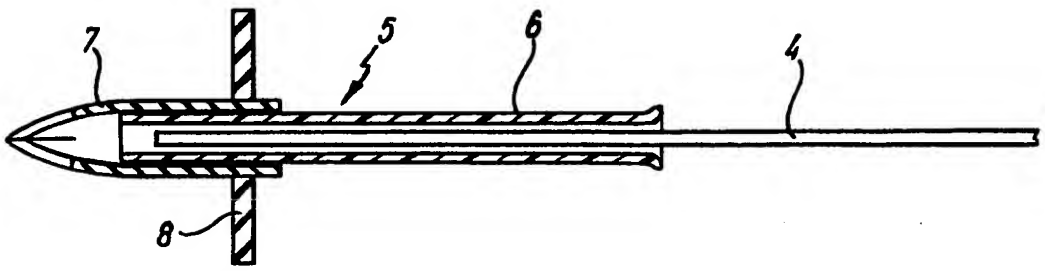

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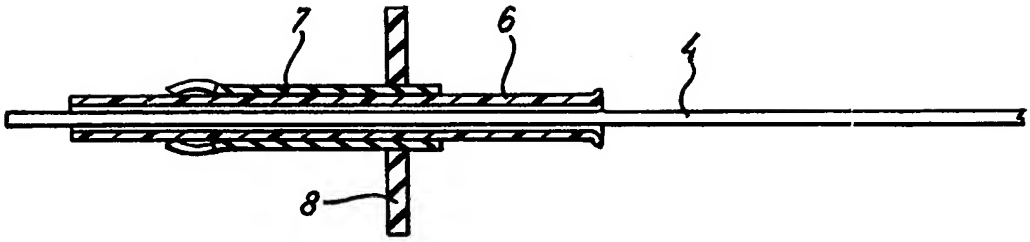
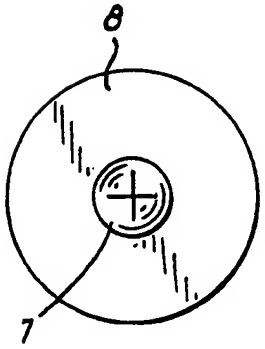


Фиг.3



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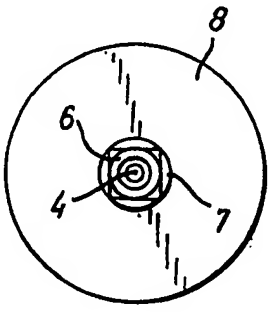

Фиг.5

SPECIFICATION

Medical instrument

This invention relates to improvements in medical instruments.

One of the most common medical procedures is the insertion of a medical instrument into a body passage, for example the insertion of a swab or catheter into the urethra, and, despite great advances having been made in the prevention of infection in many areas, this procedure has continued to cause introduction of infection into organs such as the bladder.

It is standard practice for catherisation to be performed only after the area around the passage has been thoroughly cleaned, the catheter has been sterilised and the operator has donned surgical gloves and mask, and yet infection has still been common. The reason for this has now been deduced as resulting from bacteria which are present within the body passage itself particularly at its outer end, and which it is difficult if not impossible to remove prior to insertion of the instrument. As the instrument enters the passage, therefore, it comes into contact with the bacteria and carries them along the passage with it, thus causing infection at the top of the passage. No amount of precleaning of the area external of the passage will prevent this.

A similar problem has beset the operation of taking swab samples from a desired position within a body passage, as the act of introducing the swab into the passage causes the swab to pick up bacteria before it reaches the desired position, thus preventing an accurate bacteria count from being obtained at that position. Withdrawal of the swab then picks up more bacteria, or indeed can lose some of the bacteria already on it. The taking of swab samples from a passage has therefore been rather haphazard and inaccurate.

Several proposals have previously been made to prevent the instrument carrying bacteria along the passage, but none of these has proved entirely successful. For example, U.S. Patents Nos. 3,332,424 (Minteer), 3,908,635 (Vick) and 3,908,663 (Vick) describe catheters having a tube of thin flexible material and a rigid collar secured around one end of the catheter tube. In use, these catheters are operated by placing the collar around the entrance to the body passage and pushing the tube through the collar so that the tube progressively everts along the passage. In this way movement of the tube wall relative to the passage wall is reduced so that bacteria are less likely to be carried along the passage, but bacteria can nevertheless be forced into the leading open end of the tube as it everts. These bacteria are then redeposited further up the passage on continued eversion of the tube. While these previously proposed catheters are an improvement over a basic catheter tube they still cause a degree of contamination by carrying bacteria further up the passage.

U.S. Patent No. 3,669,099 (Silverman) describes and claims a similar system to the above-described prior art in that it has everting tubing for contacting a body cavity wall, but in this case the ends of the tubing are secured and sealed to a rigid cylindrical tube surrounding the tubing, so that the tubing forms a closed toroidal chamber which is then filled with a fluid. A long cylindrical medical instrument can then be pushed through the tubing, and the pressure of fluid causes the tubing to evert as the instrument passes through it. This previously-proposed arrangement is complex as a fluid inlet must be provided in the rigid tube for injection of fluid to an appropriate pressure, and the presence of the toroidal chamber makes the apparatus rather wide and therefore somewhat uncomfortable for the patient. It is also relatively expensive to manufacture.

An object of this invention is to provide a medical instrument for insertion into a body passage, the instrument being inexpensive to produce and not unduly traumatic to the patient when in use.

According to the present invention there is provided a medical instrument for insertion into a body passage, comprising an elongate instrument body having a distal end and a proximal end, an inpervious sheath extending over the distal end of the body so that the body is slidable within the sheath, the sheath having a closed end which is openable to allow the distal end of the body to slide therethrough.

The instrument body may be, for example, a catheter or a swab.

In use, the sheath is inserted into a body passage preferably to an extent whereby it penetrates slightly beyond bacteria within the passage adjacent its outer end, so that the instrument body is isolated from such bacteria by the sheath. The body is then pushed through the closed end of the sheath to continue along the passage to the target area, and in this way bacteria is not carried into the target area by the instrument.

Preferably, the sheath is provided with stop means, such as a portion of increased diameter, for example in the form of a collar, spaced from the sheath ends to engage the area around the passage entrance and thus limit the penetration of the sheath; the stop means can be set a predetermined distance along the sheath depending on the usual extent of bacteria within the passage.

A very effective manner of providing the openable sheath end is for that end portion to be slit so that in its normal state the slit it closed to seal the sheath end, but when the distal end of the instrument body is pressed against it from within the sheath the slit opens

to define an aperture for passage of the body. For this to operate most effectively the sheath end portion should be resilient so that the slit closes again on retraction of the instrument body into the sheath; bacteria are therefore prevented from entering the sheath on removal of the instrument from the passage. In an alternative arrangement the sheath can have a membrane across its ends, the membrane being rupturable on pushing the instrument body against it.

For ease of insertion as well as for effective sealing, the end portion of the sheath is preferably tapered.

The sheath may be in one piece or may alternatively comprise a number of parts which together produce the desired features. For example the sheath may have an open-ended tubular body portion within which the instrument body slides, and a cap enveloping one end of the body portion and having an openable closed end. In any event it is preferable that the sheath should be sufficiently long to allow it in use to be held externally of the body passage thus making the instrument easy to use.

The instrument of this invention can also be modified to allow its use without the necessity for the user to wear surgical gloves and other protective clothing, by making the sheath longer than the portion of the instrument for insertion into the body passage, so that that portion of the instrument body is contained within the sheath before use. In this way the user will handle the instrument body only in areas which will not enter the passage, so bacteria will not be transferred into the passage from the user's hands by the instrument body.

To further ensure the isolation of bacteria a second sheath can be provided movable with the instrument body and connected with the first sheath in a manner allowing relative longitudinal movement between them while retaining between them a barrier against passage of bacteria to the instrument body. The sheaths may be connected in a telescopic arrangement with one of the sheaths being slidable within the other. Alternatively a collapsible connection may extend between them, for example a "concertina" connection. The second sheath may be secured to the instrument body so as to be permanently movable with it, or it may be of flexible material so that the instrument body can be gripped through the second sheath by applying finger pressure.

The invention is also an introducer for use in inserting a medical instrument into a body passage, comprising an impervious sheath having an open end to receive an elongate instrument body and having a closed end which is openable to allow the instrument body to slide therethrough.

Further according to the invention there is provided a method of introducing a medical instrument into a body passage, comprising inserting into the passage an impervious sheath for receiving the instrument body, the sheath being closed at its distal end, and passing at least a distal end portion of the instrument body through the sheath so as to penetrate the distal end of the sheath.

The sheath should be inserted into the body passage to an extent whereby its distal end penetrates beyond bacteria disposed adjacent the proximal end of the passage, so that bacteria are not carried further along the passage by the instrument body.

Embodiments of the invention will now be described by way of example with reference to the accompanying drawings, in which:

Figure 1 is a schematic diagram showing the distribution of bacteria in a female urethra;

Figure 2 is a side sectional view of a catheter with its introducer, in accordance with the invention;

Figure 3 is a side elevational view of the catheter and introducer of Fig. 2 in use;

Figure 4 is an end elevation corresponding to Fig. 2;

Figure 5 is an end elevation corresponding to Fig. 3;

Figure 6 is a side sectional view of a swab and an alternative form of the introducer, in accordance with the invention; and

Figure 7 is a side sectional view of a further alternative form of a urethral catheter and introducer, in accordance with the invention.

Referring to Fig. 1, the bladder 1 communicates with the outside through the urethra 2. The bladder 1 and upper urethra 2 are sterile, but the lower urethra and the area surrounding it are highly contaminated by bacteria 3. When the bladder is to be drained by catheterisation the external area around the urethra 2 is thoroughly cleaned but it is very difficult to clean the lower urethra internally so a considerable amount of bacteria 3 remain. Insertion into the urethra 2 of an unprotected catheter, swab or other medical instrument therefore causes the bacteria 3 to be carried further along the urethra 2 and contaminate the upper urethra and bladder if the instrument is inserted sufficiently far.

Referring now to Figs. 2 to 5, the problem of bacteria 3 being carried along the urethra 2 is obviated or mitigated by providing a catheter tube 4, of conventional plastics material, within a sheath 5 whose side walls are impervious to bacteria. The sheath 5 is formed by a plastics outer tube 6 coaxial with the catheter tube 4 and having over its distal end a latex rubber cover 7. The distal end of the cover 7 is cross-cut so as to provide a seal against passage of bacteria when in its closed position as in Figs. 2 and 4, while allowing penetration of the outer tube 6 and catheter tube 4 on application of pressure by them, as shown

in Figs. 3 and 5.

In use, the catheter is inserted, cover 7 first, into the urethra 2 until the collar 8 abuts the area around the urethra entrance and prevents further penetration; at this stage the cross-cut end of the cover is at the area marked "X" in Fig. 1. As the collar 7 is spaced from the ends of the sheath 5 the sheath can still be easily gripped by the user when fully inserted into the urethra, by holding the outer tube 6. The outer tube 6 is then pushed through the cross-cut end of the cover 7 to extend further into the urethra but not to penetrate into the bladder 1. Because of the closed end of the cover 7 during initial insertion the outer tube 6 becomes contaminated with bacteria 3 only to insignificant degree, if at all, as it extends through the cover 7.

In the final stage of insertion the catheter tube 4 is pushed through the outer tube 6 and into the bladder 1. The bladder 1 can then be drained without risk of infection.

Instead of pushing the outer tube 6 through the cross-cut end of the cover 7, the catheter tube 4 may be pushed straight into the bladder 1 through the cross-cut end. In this way there is a slightly greater risk of bladder infection but in fact it is insignificant.

The inner diameter of the outer tube 6 is the same as the outer diameter of the catheter tube 4 or slightly less, and in this way the catheter tube 4 is retained in the outer tube 6 and will not fall out during use. In an alternative, the diameter of the aperture in the rubber collar 8 can be such that it "pinches" the outer tube 6 and catheter tube 4 to achieve the same object.

It is also of importance in this embodiment of the invention that the outer tube 6 should be of greater length than the maximum distance through which the catheter tube 4 will project in use from the cover 7. In this way any contamination of the catheter tube 4 externally of the outer tube 6 will not be transferred along the outer tube 6 and into the urethra 2 or bladder 1. Further, when the catheter is used in the manner described above, the outer tube 6 should not be pushed through the cover 7 by an extent greater than the length of the cover. This further prevents any bacteria being transferred into the bladder or urethra.

Referring now to Fig. 6, a swab 9 is used instead of the catheter tube 4, and instead of providing an outer tube 6 with a rubber end cover 7, the sheath 5 is in one piece, its distal end tapering and being cross-cut to provide the same effect as the cover 7. In use, the absence of the separate outer tube 6 makes it necessary to push the swab 9 directly through the cross-cut end of the sheath 5 into the body passage. The form of the sheath 5 also protects the swab from contact with bacteria on withdrawal from the passage, as retraction of the swab 9 into the sheath 5 causes the cross-cut end to close again thus renewing the barrier to bacteria. The swab sample taken therefore gives an accurate reading from the desired area.

Referring now to Fig. 7, the catheter tube 4 has two outer tubes 10 and 11 disposed coaxially around it. The second outer tube 11 is of smaller diameter than the first outer tube 10 and extends into it in telescopic fashion at 12. The first tube 10 has at its opposite end a rubber cover 7 held on the first tube 10 by a rubber collar 8 which also acts as a stop member as in Figs. 2 to 5; the cover 7 is cross-cut at its distal end.

The free end of the second sheath 11 is secured to the tube 4 by a tight-fitting sleeve 13 which prevents relative movement between the tube 4 and sheath 11.

The sheaths 10 and 11 are made of rigid plastics material while the tube 4 is of pliable plastics material and the cover 7 is of soft rubber.

The instrument of Fig. 7 is used in similar fashion to those of Figs. 2 to 5, except that the catheter tube 4 is not handled directly, being protected by the tubes 10 and 11. When the catheter tube 4 is to be pushed through into the urethra this is achieved by gripping and pushing the second tube 11 into the first tube 10.

The rigidity of the outer tubes 10 and 11 allows the pliable tube 4 to be easily introduced. A thin plastics cover 14 is secured to both outer tubes 10 and 11 to prevent bacteria entering between the tubes and thus contaminating the tube 4.

The arrangement can be readily modified at the end 7 to allow it to be used in, for example, epidural operations.

CLAIMS

1. An introducer for use in a body passage, comprising an impervious sheath having an open end to receive an elongate instrument body and having a closed end which is openable to allow the instrument body to slide therethrough.

2. An introducer according to Claim 1, wherein the sheath is provided with stop means for limiting the extent of penetration of the sheath into a body passage.

3. An introducer according to Claim 2, wherein the stop means is a portion of increased diameter spaced from the sheath ends.

4. An introducer according to Claim 1, 2 or 3, wherein the closed end of the sheath is slit so that in its normal state the slit is closed to provide a seal but is openable on pressure from within the sheath to define an aperture.

5. A medical instrument for insertion into a body passage, comprising an elongate instrument body having a distal end and a proximal end, an impervious sheath extending over the distal end of the body so that the

body is slidable within the sheath, the sheath having a closed end which is openable to allow the distal end of the body to slide therethrough.

6. A medical instrument according to Claim 5, wherein the instrument body is a catheter or a swab.

7. A medical instrument according to Claim 5 or 6, wherein a second sheath is provided movable with the instrument body and connected with the first sheath in a manner allowing relative longitudinal movement between them while retaining between them a barrier against passage of bacteria.

8. A method of introducing a medical instrument into a body passage, comprising inserting into the passage an impervious sheath for receiving the instrument body, the sheath being closed at its distal end, and passing at least a distal end portion of the instrument body through the sheath so as to penetrate the distal end of the sheath.

9. A method according to Claim 9, wherein the sheath is inserted into the body passage to an extent whereby its distal end penetrates beyond bacteria disposed adjacent the proximal end of the passage.

10. An introducer for use in a body passage substantially as hereinbefore described with reference to and as shown in Figs. 2, 3, 4 and 5 of the accompanying drawings.

11. An introducer for use in a body passage substantially as hereinbefore described with reference to and as shown in Fig. 6 of the accompanying drawings.

12. An introducer for use in a body passage substantially as hereinbefore described with reference to and as shown in Fig. 7 of the accompanying drawings.

13. A medical instrument substantially as hereinbefore described with reference to and as shown in Figs. 2, 3, 4 and 5 of the accompanying drawings.

14. A medical instrument substantially as hereinbefore described with reference to and as shown in Fig. 6 of the accompanying drawings.

15. A medical instrument substantially as hereinberfore described with reference to and as shown in Fig. 7 of the accompanying drawings.

16. A method of introducing a medical instrument into a body passage, substantially as hereinbefore described with reference to the accompanying drawings.

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